Patent

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## **CLAIMS**

- 1. A method of treating inflammation comprising administering a therapeutic amount of a nonsteroidal anti-inflammatory drug condensation aerosol, having an MMAD less than 3 μm and less than 5% nonsteroidal anti-inflammatory drug degradation products, to a patient by inhalation, upon activation by the patient of the formation of, and delivery of, the condensation aerosol.
- 2. The method of claim 1, wherein said condensation aerosol is formed by
- a. volatilizing a nonsteroidal anti-inflammatory drug under conditions effective to produce a heated vapor of the nonsteroidal anti-inflammatory drug; and
- b. condensing the heated vapor of the nonsteroidal anti-inflammatory drug to form condensation aerosol particles.
- 3. The method according to claim 2, wherein said administration results in a peak plasma concentration of said nonsteroidal anti-inflammatory drug in less than 0.1 hours.
- 4. The method of claim 2, wherein the nonsteroidal anti-inflammatory drug is selected from the group consisting of indomethacin, ketoprofen, celcoxib, rofecoxib, meclofenamic acid, fenoprofen, diflunisal, tolfenamic acid, naproxen, ibuprofen, flurbiprofen, or nabumetone.
- 5. The method according to claim 1, wherein the administered aerosol is formed at a rate greater than 0.5 mg/second.
- 6. The method according to claim 1, wherein at least 50% by weight of the condensation aerosol is amorphous in form.
- 7. A method of treating inflammation comprising administering a therapeutic amount of an indomethacin, ketoprofen, celcoxib, rofecoxib, meclofenamic acid, fenoprofen, diflunisal, tolfenamic acid, naproxen, ibuprofen, flurbiprofen, or nabumetone condensation aerosol, having an MMAD less than 3 µm and less than 5% indomethacin, ketoprofen, celcoxib, rofecoxib, meclofenamic acid, fenoprofen, diflunisal, tolfenamic acid, naproxen, ibuprofen, flurbiprofen, or nabumetone degradation products, to a patient

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by inhalation, upon activation by the patient of the formation of, and delivery of, the

8. The method of claim 7, wherein said condensation aerosol is formed by

condensation aerosol.

- a. volatilizing indomethacin, ketoprofen, celcoxib, rofecoxib, meclofenamic acid, fenoprofen, diflunisal, tolfenamic acid, naproxen, ibuprofen, flurbiprofen, or nabumetone under conditions effective to produce a heated vapor of indomethacin, ketoprofen, celcoxib, rofecoxib, meclofenamic acid, fenoprofen, diflunisal, tolfenamic acid, naproxen, ibuprofen, flurbiprofen, or nabumetone; and
- b. condensing the heated vapor of indomethacin, ketoprofen, celcoxib, rofecoxib, meclofenamic acid, fenoprofen, diflunisal, tolfenamic acid, naproxen, ibuprofen, flurbiprofen, or nabumetone to form condensation aerosol particles.
- 9. The method according to claim 8, wherein said administration results in a peak plasma concentration of said indomethacin, ketoprofen, celcoxib, rofecoxib, meclofenamic acid, fenoprofen, diflunisal, tolfenamic acid, naproxen, ibuprofen, flurbiprofen, or nabumetone in less than 0.1 hours.
- 10. The method according to claim 7, wherein at least 50% by weight of the condensation aerosol is amorphous in form.
- 11. The method according to claim 7, wherein said condensation aerosol has an inhalable aerosol mass density greater than 5 mg/L when delivered.
- 12. The method according to claim 7, wherein said condensation aerosol has an inhalable aerosol mass density greater than 7.5 mg/L when delivered.
- 13. The method according to claim 7, wherein said condensation aerosol has an inhalable aerosol mass density greater than 10 mg/L when delivered.
- 14. A method of administering a nonsteroidal antiinflammatory drug to a patient to achieve a peak plasma drug concentration rapidly, comprising administering to the patient by inhalation an aerosol of a nonsteroidal anti-inflammatory drug having less than 5%

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nonsteroidal antiinflammatory drug degradation products and an MMAD less than 3 microns wherein the peak plasma drug concentration of the nonsteroidal anti-inflammatory drug is achieved in less than 0.1 hours.

- 15. A method of administering indomethacin, ketoprofen, celcoxib, rofecoxib, meclofenamic acid, fenoprofen, diflunisal, tolfenamic acid, naproxen, ibuprofen, flurbiprofen, or nabumetone to a patient to achieve a peak plasma drug concentration rapidly, comprising administering to the patient by inhalation an aerosol of indomethacin, ketoprofen, celcoxib, rofecoxib, meclofenamic acid, fenoprofen, diflunisal, tolfenamic acid, naproxen, ibuprofen, flurbiprofen, or nabumetone having less than 5% indomethacin, ketoprofen, celcoxib, rofecoxib, meclofenamic acid, fenoprofen, diflunisal, tolfenamic acid, naproxen, ibuprofen, flurbiprofen, or nabumetone degradation products and an MMAD less than 3 microns wherein the peak plasma drug concentration of indomethacin, ketoprofen, celcoxib, rofecoxib, meclofenamic acid, fenoprofen, diflunisal, tolfenamic acid, naproxen, ibuprofen, flurbiprofen, or nabumetone is achieved in less than 0.1 hours.
- 16. A kit for delivering a drug aerosol comprising:
  - a) a thin coating of a nonsteroidal antiinflammatory drug composition and
  - b) a device for dispensing said thin coating as a condensation aerosol.
- 17. The kit of claim 16, wherein the nonsteroidal antiinflammatory drug of the composition is selected from the group consisting of indomethacin, ketoprofen, celcoxib, rofecoxib, meclofenamic acid, fenoprofen, diflunisal, tolfenamic acid, naproxen, ibuprofen, flurbiprofen, or nabumetone
- 18. The kit of claim 16, wherein the device for dispensing said coating of a nonsteroidal antiinflammatory drug composition as an aerosol comprises
  - (a) a flow through enclosure,
- (b) contained within the enclosure, a metal substrate with a foil-like surface and having a thin coating of a nonsteroidal antiinflammatory drug composition formed on the substrate surface,

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(c) a power source that can be activated to heat the substrate to a temperature effective to volatilize the nonsteroidal antiinflammatory drug composition contained in

said coating, and

(d) inlet and exit portals through which air can be drawn through said device by

inhalation,

wherein heating the substrate by activation of the power source is effective to form a nonsteroidal antiinflammatory drug vapor containing less than 5% nonsteroidal antiinflammatory drug degradation products, and drawing air through said chamber is effective to condense the nonsteroidal antiinflammatory drug vapor to form aerosol

particles wherein the aerosol has an MMAD of less than 3 microns.

19. The kit according to claim 18, wherein the heat for heating the substrate is

generated by an exothermic chemical reaction.

20. The kit according to claim 19, wherein said exothermic chemical reaction is

oxidation of combustible materials.

21. The kit according to claim 18, wherein the heat for heating the substrate is

generated by passage of current through an electrical resistance element.

22. The kit according to Claim 18, wherein said substrate has a surface area

dimensioned to accommodate a therapeutic dose of a nonsteroidal antiinflammatory drug

composition in said coating.

23. The kit according to claim 16, wherein a peak plasma concentration of

anonsteroidal antiinflammatory drug is obtained in less than 0.1 hours after delivery of

the condensation aerosol to the pulmonary system.

24. The kit of claim 16, further including instructions for use.

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